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4/15/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 11 1997

VIA FEDERAL EXPRESS

WARNING LETTER

Mr. Uwe G. Peck
Managing Director/Co-Owner
Normed Medizin-Technik GmbH
Ulrichstrasse 7
D-78532 Tuttlingen, Germany

Dear Mr. Peck:

During an inspection of your firm located in Tuttlingen, Germany on March 5, 1997, our investigator determined that your firm manufactures surgical instruments. These are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to maintain a device history record to demonstrate that the device is manufactured in accordance with the device master record, that includes, or refers to the location of, the dates of manufacture, the quantity manufactured, the quantity released for distribution, and any control number used, as required by 21 CFR 820.184. For example, although the Standard Operating Procedure (SOP) for the boil test requires testing of newly introduced products and those having an identified problem, there are no records that the testing is performed.

2. Failure to maintain a device master record prepared, dated, and signed by a designated individual for each type of device, as required by 21 CFR 820.181. For example, at least of the drawings from the device master records have not been signed.

3. Failure to, where necessary, test for conformance with device specifications each production run, lot or batch prior to release for distribution; to select a device, where practical, from a production run, lot or batch and test under simulated use conditions; and, to base the sampling plans for checking, testing, and release of a device on an acceptable statistical rationale, as required by 21 CFR 820.160. For example:

   (a) The [redacted] are not subjected to a finished device test for conformance to specifications, and

   (b) The sample size used to inspect [redacted] and plates is not based on a valid statistical rationale.

4. Failure to receive, store, and handle in a manner designed to prevent damage, mixup, contamination, and other adverse effects components used in manufacturing, as required by 21 CFR 820.80. For example, procedures are not adequate to assure that devices are correctly identified to prevent mixups. Approximately 60 sets of [redacted] etched with one catalog number, were in various sorts of containers identified with different catalog numbers.

5. Failure to clearly identify and segregate from accepted components, all obsolete, rejected, or deteriorated components, as required by 21 CFR 820.80(b). For example, warehouse controls are not established to assure that devices not approved for release are separated/segregated from devices which are approved for release.

6. Failure to implement planned and periodic audits of the quality assurance program to verify compliance with the quality assurance program, as required by 21 CFR 820.20(b). For example, audits of the quality assurance program have not been scheduled or conducted.

This letter is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Given the serious nature of these violations of the Act, all devices manufactured by Normed Medizin-Technik GmbH, Ulrichstrasse 7, D-78532 Tuttlingen, Germany may be detained upon entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from this detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that the response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections has been verified, your products may resume entry into this country.

Please notify this office in writing of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If documentation is not in English, please provide an English translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement I, General Surgery Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Carol Shirk.

Sincerely yours,

for Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health